NOV - 8 2011

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342
	Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer
Date Prepared:	July 15, 2011

DEVICE NAME

Trade/Proprietary Name:	Calix ™ PC Spinal Implant System
Common Name(s):	Intervertebral Body Fusion Device Vertebral Body Replacement Device
Classification Name(s):	Intervertebral Fusion Device with Bone Graft, Cervical Spinal Vertebral Body Replacement Device
Device Class:	Class II
Classification(s):	§888.3080, §888.3060
Product Codes(s):	ODP, MQP

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

PREDICATE DEVICES

- BAK/Cervical Interbody Fusion System (P980048/S3)
- Spinal Elements Crystal (K073351)
- Calix Spinal Implant System K083637)

INTENDED USE

When used as a vertebral body replacement, the X-spine Calix PC System is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral

body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The Calix device, when used as a vertebral body replacement, can be packed with either allograft or autograft.

When used as an intervertebral body fusion device, the X-spine Calix PC System is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. Patients should receive 6 weeks non-operative treatment prior to treatment with the Calix intervertebral body fusion device.

For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical, thoracic or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

DEVICE DESCRIPTION

The X-spine Calix PC System is a generally box-shaped device with various holes located throughout its geometry and teeth on the superior and inferior surfaces. The device is made from polyetheretherketone (Invibio PEEK-Optima LT1). The devices contain radiographic markers made from tantalum per ASTM F560. The technological difference between this system and the current Calix Spinal Implant System is the addition of a commercially pure titanium (CP Ti) coating per ASTM F1580 applied to the superior and inferior surfaces of each device.

NONCLINICAL TESTING TO SUPPORT SUBSTANTIAL EQUIVALENCE

To establish device performance, the following standardized tests were conducted on full device constructs:

ASTM F2077 – *Test Methods for Intervertebral Body Fusion Devices*

- Static and dynamic axial compression
- Static torsion

Expulsion testing as suggested by FDA Guidance – *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*

To establish coating characterization, the following standardized tests were conducted on coated test coupons:

ASTM F1044 – *Standard Test Method for Shear Testing of Calcium Phosphate and Metallic Coatings*

- Static and dynamic shear

ASTM F1147 – *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings*

- Static tension

Abrasion testing as suggested by FDA Guidance – *Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*

BASIS OF SUBSTANTIAL EQUIVALENCE

In summary, biomechanical testing results indicate that the Calix PC Spinal Implant System is substantially equivalent to predicate device performance and is as safe, as effective, and performs at least as safely and effectively as the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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X-Spine Systems, Inc.
% David Kirschman, MD
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K112036
Trade/Device Name: Calix™ PC Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: October 25, 2011
Received: October 27, 2011

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112036

Device Name: Calix PC™ Spinal Implant System

Indications for Use:

When used as a vertebral body replacement, the X-spine Calix PC System is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The Calix device, when used as a vertebral body replacement, can be packed with either allograft or autograft.

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For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical, thoracic or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112036